REMARKS

There are 64 claims pending in the present, divisional, application.

IDS Matter

The Office Action has stated the requirements of a proper IDS statement at page 2 thereof and indicated applicant has not submitted same. Applicant did, in fact, submit a complete IDS statement, including a description of 18 references, a completed PTO/SB/08A (1449 listing) as well as copies of each of the listed references. After contacting the Examiner by telephone on April 19, 2005 (for clarification of the IDS objection), applicant now understands that a EP search report was inadvertently included in the references attached to the search report (and was not listed within the 1449 sheet). As applicant never intended said EP search report to be a part of his IDS statement, non-inclusion of said references within the scope of applicant's disclosure and Examiner's consideration is indeed acceptable to applicant.

Section 112 Rejections

Claim 1 and 43 have now been amended in response to the Office Actions Section 112 rejections of said claims. More specifically, the term "performance enhancing medicament, which the Office Action described as indefinite, has been replaced with the term "*pressure equalization* performance enhancing medicament" so as to clearly describe exactly what type of performance is enhanced –To wit, the eustachian tube's function of equalizing pressure between the middle ear and ambient atmospheric pressure.

Applicant's specification clearly supports and describes this term and function at, for example a page 6, lines 12 to 22 of applicant's specification, the pressure equalization function of the eustachian tube, albeit well known to the art, is clearly explained.

> As mentioned above, the eustachian tube is specifically adapted to provide communication between the middle ear (a sealed chamber), and ambient atmospheric pressure, by providing a pathway between the tympanic cavity

> and the nasopharynx. Thus the auditory tube serves as a pressure equalization means for the middle ear. However, in order to provide this equalization function, and, at the same time, allow proper middle ear sound conduction, the eustachian tube, and the pathway it provides between the middle ear and the nasopharynx, are ordinarily closed. The lumen of the tube, as discussed below, is ordinarily open only during the act of swallowing and other movements that cause contraction of the attached musculature.

At page 5, lines 14 to 27 of applicant's specification, the effect and mode of action of applicant's claimed composition in enhancing the afore-mentioned eustachian tube function (pressure equalization) is clearly described.

> The lipid surfactants utilized in practicing the method of the present invention are selected to be present in an amount sufficient to effectively reduce the surface tension of the liquid/air interface of the epithelial surface to which they are applied, while the spreading agents are present in an amount sufficient to effectively distribute the lipids upon said surface. The term, "effectively reduce surface tension" as utilized throughout this application and in the claims, refers to that weight percentage range of lipid which, when present in said mixture of lipid crystals, provides a clinically significant decrease in eustachian tube opening pressure so as to allow increased pressure equalization function. The term, "effectively distribute the lipids upon said surface" refers to that weight percentage range of spreading agent that is required in order to provide adequate spreading and distribution of the lipids so as to form an amorphous spread film upon the epithelial lined surfaces of the lumen so that the lipid surfactant effects sufficient lumenal surface area enabling the afore-mentioned reduction in opening pressure.

In regard to ascertaining the degree of enhancement of eustachian tube pressure equalization function effected by applicant's claimed composition, it is respectfully submitted that applicant's specification provides clear disclosure and, in fact quantification of such effects.

At page 29, lines 19 to 28 of applicant's specification, the pressure equalization enhancement of mammalian eustachian tubes treated with applicant's claimed composition is clearly demonstrated.

EFFECT OF AEROSOLIZED LIPID CRYSTALS ON PASSIVE OPENING

PRESSURE OF THE EUSTACHIAN TUBE IN AN ANIMAL MODEL

The aerosolized lipid crystal mixture described in "Example V", above, was administered, through the nose, to Mongolian Gerbils and Wistar Mice. Administration of the mixture resulted in a reduction, from an initial opening pressure of 36.82+/- 2.03 mmHG to 29.16+/-2.67 –an approximately 18% reduction in the Mongolian Gerbils-- and from an initial opening pressure of 43.1+/- 1.43 mmHG to 32.1+/-2.21 –a reduction in opening pressure of approximately 23% in Wister Mice--. Therefore, the composition and method of the present invention effectively increased eustachian tube patency by means of an exogenous nasally administered surfactant.

Thus it is respectfully submitted that the term "pressure equalization performance enhancing medicament" now appearing in claim 1 (amended) and the cancellation of the term "performance enhancing" now removes the indefinite nature of said later term from claim 1. Thus it is submitted that the section 112 rejection of claim 1 should now be withdrawn.

Claim 43 was also rejection under 37 USC 112 as being indefinite for failing to particularly point out and distinctly claim the subject matter regarded by applicant as his invention. More specifically, the Office Action complained that the term "said Eustachian tube and middle ear" were without antecedent basis. Applicant's claim 43 has now been amended so as to eliminate said antecedent term. Therefore, it is respectfully submitted that the section 112 rejection of claim 43 should now be withdrawn.

DOUBLE PATENTING REJECTIONS

Claims 1 - 19, 20 - 64 have been rejected under the judicially created doctrine of obviousness-type double patenting over claims 55 - 77 and 78 - 108 (respectively) of US Patent No. 6,616,913 B1. Enclosed herewith, is a assignment of the instant application from Alan Mautone to Scientific Development and Research, Inc. US Patent No. 6,616,913 B1 has already been assigned (of record) to the same assignee, Scientific Development and Research, Inc. Enclosed herein is a fully executed terminal disclaimer in compliance with 37 CFR 1.321(c) wherein applicant disclaims the terminal extent of the term of any patent granted upon the present application **that would extend beyond the statutory term of US Patent No. 6, 616,913 B1.** . Therefore, it is respectfully requested that the double patenting

rejection of pending claims 1 - 19, 20 - 64 over claims 55 - 77 and 78 - 108 (US Patent Nol. 6,616,913 B1) now be withdrawn.

Claims 1 - 64 have been rejected under the judicially created doctrine of obviousness-type double patenting over claims 45 - 86 and 111 - 133 of US Patent No. 6,645,467 B1. The '467 application relates to a composition, process and method for treatment for decreasing mammalian upper respiratory system airway resistance. The subject patent is totally silent as to the anatomy, diseases or application of crystals to the middle ear. In fact, none of these terms is ever mentioned in said patent. Further more, neither the ear or the eustachian tube are components of the respiratory system. Therefore, one seeking information in regard to treatment of pathology resident in the middle ear or eustachian tube (e.g., otitis media) would not be expected to be drawn to, utilize or read the '467 patent for those purposes. Therefore, it is respectfully submitted that the obviousness-type double patenting rejection of applicant's claims 1 - 64 over claims 45 - 86 and 111 - 133 of US patent No. 6,645,467 B1 is improper and should now be withdrawn. .

Claims 1 - 64 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 43 - 84 and 108 - 130 of copending Application No. 2002/0076383 (10/011626) . The '626 application relates to the treatment of otitis externa, a condition separate and apart from otitis media (to which the present application relates). Otitis media, a condition of the outer ear –a portion of the ear anatomically distinct, and, most importantly, separated by a physical barrier (the ear drum) from the middle ear. Thus, it is not surprising that the crystals disclosed in the '626 application **are never disclosed as having any utility in treatment of middle ear, otitis media or eustachian tube pathologies. In fact, the '626 application, disparate with the present application, instills the disclosed crystals directly into the external auditory canal (the outer ear canal open to the external environment), via simple application through the outer ear.** Application in the manner disclosed by the '626 application, intended to treat conditions of the outer ear *would never be expected to reach, lot alone treat the middle ear or eustachian tube (unless a punctured ear drum were present).* One

seeking treatment medicaments for middle ear and/or eustachian tube pathology would not ordinarily utilize the teachings of US Patent application10/011,626 since said application simply does not relate to middle ear, eustachian tube and related otitis media pathologies. Therefore, it is respectfully submitted that the obviousness-type double patenting rejection of applicants pending claims 1 - 64 over claims 49 - 102 of US Patent application 10/011,626 is without proper basis and should now be withdrawn. Therefore, it is respectfully requested that the double patenting rejection of pending claims 1 - 64 over pending claims 43 - 84 and 108 - 130 of copending US Patent Application No. 10/011,626 should now be withdrawn.

Claims 1 - 64 have been rejected under the judicially created doctrine of obviousness-type double patenting over claims 49 - 102 of US Patent No. 6,521,213. The '213 patent relates to the treatment of otitis externa, a condition separate and apart from otitis media (to which the present application relates). Otitis media, a condition of the outer ear –a portion of the ear anatomically distinct, and, most importantly, separated by a physical barrier (the ear drum) from the middle ear. Thus, it is not surprising that the crystals disclosed in the '213 patent **are never disclosed as having any utility in treatment of middle ear, otitis media or eustachian tube pathologies. In fact, the '213, disparate with the present application, instills the disclosed crystals directly into the external auditory canal (the outer ear canal open to the external environment), via simple application through the outer ear.** Application in the manner disclosed by the '213 patent, intended to treat conditions of the outer ear *would never be expected to reach, lot alone treat the middle ear or eustachian tube (unless a punctured ear drum were present).* One seeking treatment medicaments for middle ear and/or eustachian tube pathology would not ordinarily utilize the teachings of US Patent No. 6,521,213 since said patent simply does not relate to middle ear, eustachian tube and related otitis media pathologies. Therefore, it is respectfully submitted that the obviousness-type double patenting rejection of applicants pending claims 1 - 64 over claims 49 - 102 of US Patent No. 6,521,213 is without proper basis and should now be withdrawn.

Claims 20 - 64 have been rejected under the judicially created doctrine of

obviousness-type double patenting over claims 1 - 20 of US Patent No. 5,306,483. The 5,306,483 patent relates to relates to a process for preparing lipid crystals in combination with a therapeutically active agent *effective in the treatment of* ***pulmonary conditions, such as, for example, pulmonary insufficiency syndrome and asthma.*** Nowhere within the '483 application is there any suggestion that the disclosed composition or method might have any application, whatsoever, to middle ear conditions (such as otitis media) or treatment of the eustachian tube. Since the '483 patent is concerned with pulmonary applications, it is not surprising that the ear (and, middle ear) eustachian tube and otitis media are words that never appear in said patent. In addition, the '483 patent does not suggest, disclose or mention **nasal inhalation** of the disclosed crystals. This is expected in that nasal inhalation that, in accordance with the pending application, allows access to the eustachian tube and middle ear, would be of little or no use in practicing the compositions and/or methods of the '483 patent. Simply put, the '483 patent indicates use, application, indications and routes of administration for the disclosed mixture of lipid crystals in a totally disparate manner than taught and claimed in the instant application. One wishing to find such crystals for application to and treatment of middle ear and eustachian tubes simply could not be expected to look to said patent for appropriate information. Therefore, it is respectfully submitted that the obviousness-type double patenting rejection of applicants claims 20 - 64 over claims 1 - 20 of US Patent No. 5,306,483 is without proper basis and should now be withdrawn.

In view of the foregoing Remarks and amendments, it is respectfully submitted that applicant's pending claims 1 - 64 are now in condition for allowance, early notice of which would be earnestly appreciated.

Enclosed herewith are fully executed terminal disclaimers in compliance with 37 CFR 1.321(c) wherein applicant disclaims the terminal extent of the term of any patent granted upon the present application that would extend beyond the statutory term of any patent that might issue from: US Patent No. 6,616,913 B and the $65.00 fee required in accordance with 37 CFR 1.20(d).

Also enclosed is a fully executed assignment of the instant application to

Scientific Design and Research, Inc. as well as the required fee for said disclaimer and the required $40.00 fee (37 CFR 1.21(h)) and cover sheet necessary for recording of said assignment. It is believed that no further fees are required upon the filing of this amendment.

Respectfully submitted,

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